

**REMARKS**

Claims 2 and 4 have been cancelled.

Claim 1 has been amended to recite “[a] mutant of a recombinant microorganism selected from the group consisting of *Sinorhizobium meliloti* IFO 14782/pVK601, *Sinorhizobium meliloti* PY-C341-K1, and *Sinorhizobium meliloti* PY-EGC1 capable of producing vitamin B<sub>6</sub> having a plasmid expressing a recombinant pyridoxol 5'-phosphate synthase polypeptide, said plasmid being selected from the group consisting of pVK100, pRK290, pLAFRI, and RSF1010 whereby the recombinant microorganism has acquired a phenotypic property of histidine requirement or glycine resistance, or a combination of the phenotypic properties thereof.” Support for this amendment is found in the specification at, for example, page 2, lines 1-5; page 3, lines 1-6; page 3, line 23 to page 4, line 18; page 5, lines 9-16; in Examples 1-5; and in original claims 1, 3, and 5. See *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l) (8<sup>th</sup> ed. Rev. 5, August 2006, pp. 600-92 and 600-84).

Claims 3 and 5 have been amended to recite the phrase “mutant of a.” Claims 6 and 7 have been amended to recite “mutant” instead of “microorganism.” Claim 6 has also been amended to recite “comprises” instead of “comprising.” These amendments are for clarification purposes only and do not change the scope of the claims in any way.

Claim 3 has also been amended to recite “wherein a polynucleotide sequence encoding said pyridoxol 5'-phosphate synthase polypeptide is cloned into plasmid pVK100.” Support for this amendment is found in the specification at, for example, page 3, lines 1-6; in Examples 1-5; and in original claims 1 and 3. (*Id.*)

New claim 8 recites a "mutant of a recombinant microorganism according to claim 3, wherein a recombinant plasmid comprising the pyridoxol 5'-phosphate synthase gene is pVK601." Support for this amendment is found in the specification at, for example, page 7, lines 8-20; in Example 1; and in Figure 1. *See id.*

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

#### **INTERVIEW SUMMARY**

The Examiner is thanked for the courtesies extended during a telephonic Interview conducted with the undersigned on March 7, 2007. During the interview, the rejections under 35 USC § 112, first paragraph, and the foregoing amendments were discussed. The Examiner agreed that the amendments presented above would likely place the application in condition for allowance. Therefore, in view of the amendments and remarks below, withdrawal of the rejections and allowance of the claims are respectfully requested.

#### **§112, First Paragraph Rejections:**

##### **1. Written Description**

Claims 1-7 have been rejected under 35 U.S.C. §112, first paragraph. (Paper No. 20061205 at 2). In making the rejection, the Examiner asserted that claims 1-7 "contain[] subject matter, which was not described in specification ...." (*Id.*). The Examiner further asserted that "[t]he specification discloses that the coding region of the pdxJ gene from *S. meliloti* IFO14782, which encodes pyridoxol 5-phosphate synthase, was obtained using PCR primers of SEQ ID NO: 1 and SEQ ID NO: 2 (see Example 1 of the specification)," and "[t]he specification discloses *S. meliloti* IFO

14782/pVKP601, *S. meliloti* PY-C341K1, and *S. meliloti* PY-EGC 1, which produced more pyridoxol compared to the parent strain *S. meliloti* IF014782 (DSM 10226) (see Examples 1-5 and Table 1).” (*Id.*). The Examiner also asserted that “[t]he claims are genus claims drawn to a genus of mutant recombinant microorganisms of the genus *Sinorhizobium* capable of producing vitamin B<sub>6</sub>, and a genus of pdxJ genes of any nucleotide sequence and structure from any biological source.” (*Id.*). The Examiner then concluded that “one of skill in the art would not recognize that applicants were in possession of a genus of recombinant microorganisms of the genus *Sinorhizobium* capable of producing vitamin B<sub>6</sub>, and a genus of pdxJ genes of any nucleotide sequence and structure from any biological source,” and “[t]here is no known or disclosed correlation between the coding region of a polynucleotide encoding pyridoxol 5-phosphate synthase and the structure of the non-described promoter regions, regulatory elements, and untranslated regions.” (*Id.* at 3-4).

Initially, we note that there is a ***strong presumption*** that an adequate written description of the claimed invention is present in an application as filed. See *In re Wertheim*, 191 USPQ 90, 97 (CCPA 1976); and MPEP §2163(II)(A). Further, an applicant may show possession of the claimed invention by describing it using descriptive means such as, for example, words, structures, figures, diagrams and formulas. See MPEP §2163(I). Moreover, a proper written description analysis requires an analysis of the understanding of an ordinarily skilled artisan at the time of the invention. See MPEP § 2163(II)(A)(2); see also *Wang Labs. v. Toshiba Corp.*, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993).

Furthermore, the written description requirement for a claimed genus may be satisfied by sufficient description of a **representative number of species**. See *Regents of University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); and MPEP § 2163 (II)(A)(3)(a)(ii). In fact, there are situations where even one species can adequately support a genus. See *In re Rasmussen*, 211 USPQ 323, 326-27 (CCPA 1981).

With a view towards furthering prosecution, however, claim 1 has been amended to recite “[a] mutant of a recombinant microorganism selected from the group consisting of *Sinorhizobium meliloti* IFO 14782/pVK601, *Sinorhizobium meliloti* PY-C341-K1, and *Sinorhizobium meliloti* PY-EGC1 capable of producing vitamin B<sub>6</sub> having a plasmid expressing a recombinant pyridoxol 5'-phosphate synthase polypeptide, said plasmid being selected from the group consisting of pVK100, pRK290, pLAFRI, and RSF1010 whereby the recombinant microorganism has acquired a phenotypic property of histidine requirement or glycine resistance, or a combination of the phenotypic properties thereof.” And, claims 2 and 4 have been cancelled.

As amended, claim 1 recites **specific recombinant microorganisms**, namely *Sinorhizobium meliloti* IFO 14782/pVK601, *Sinorhizobium meliloti* PY-C341-K1, and *Sinorhizobium meliloti* PY-EGC1, which the Examiner conceded are described. (Paper No. 20061205 at 2). In addition, amended claim 1 recites **specific plasmids** expressing the recombinant pyridoxol 5'-phosphate synthase polypeptide, namely pVK100, pRK290, pLAFRI, and RSF1010. Moreover, claim 1, as amended, is specifically tied to a recited function, namely that the recombinant microorganism has “a phenotypic property of histidine requirement or glycine resistance, or a combination of

the phenotypic properties thereof." Support for these amendments is found virtually *in haec verba* in the specification. (See, e.g., Specification page 2, lines 1-5; page 3, lines 1-6; page 3, line 23 to page 4, line 18; page 5, lines 9-16; in Examples 1-5; and in original claims 1, 3, and 5). Accordingly, the recombinant microorganisms recited in claim 1 are specifically tied to a function/phenotypic property. Thus, there is a built-in tie between the recited recombinant microorganisms and function. Moreover, the specification exemplifies ways to obtain the currently claimed mutant recombinant microorganisms. (See, e.g., page 3 , line 21 - page 5, line 16, Examples 1-5, and Figure 1). Nothing more need be provided. Thus, in view of these amendments, it is respectfully submitted that the claims fully satisfy the written description requirement.

In view of the foregoing, it is respectfully submitted that the rejection has been rendered moot and should be withdrawn.

## **2. Enablement**

Claims 1-7 have been rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. (Paper No. 20061205 at 4). In making the rejection, the Examiner acknowledged that "[t]he specification discloses that the coding region of the pdxJ gene from *S. meliloti* IF014782, which encodes pyridoxol 5-phosphate synthase, was obtained using PCR primers of SEQ ID NO: 1 and SEQ ID NO: 2 (see Example 1 of the specification)," and "[t]he specification discloses *S. meliloti* IF0 14782/pVKP601, *S. meliloti* PY-C341K1, and *S. meliloti* PY-EGCI, which produced more pyridoxol compared to the parent strain *S. meliloti* IF014782 (DSM 10226) (see Examples 1-5 and Table 1)." (*Id.*).

The Examiner, however, asserted that "the specification does not provide guidance, prediction, and working examples for making any mutant recombinant microorganisms of the genus *Sinorhizobium* capable of producing vitamin B<sub>6</sub> having any recombinant plasmid with any pdxJ gene of any nucleotide sequence and structure from any biological source." (*Id.*).

Initially, we note it is the Examiner's burden to demonstrate that a specification is not sufficiently enabling. *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). To carry his/her burden, the Examiner must identify and clearly articulate the factual bases and supporting evidence that allegedly establish that undue experimentation would be required to carry out the claimed invention. *Id.* at 370. It is well established that claims must be separately analyzed. *Ex parte Jochim*, 11 USPQ2d 561 (BPAI 1988).

With a view towards furthering prosecution, claim 1 has been amended as noted above. As amended, claim 1 recites ***specific recombinant microorganisms***, namely *Sinorhizobium meliloti* IFO 14782/pVK601, *Sinorhizobium meliloti* PY-C341-K1, and *Sinorhizobium meliloti* PY-EGC1, which the Examiner conceded are disclosed, and presumably enabled. (Paper No. 20061205 at 4). In addition, amended claim 1 recites ***specific plasmids*** expressing the recombinant pyridoxol 5'-phosphate synthase gene, namely pVK100, pRK290, pLAFRI, and RSF1010. Moreover, claim 1, as amended, is specifically tied to a recited function, namely that the recombinant microorganism has "a phenotypic property of histidine requirement or glycine resistance, or a combination of the phenotypic properties thereof." With these amendments, it is respectfully submitted that the Examiner's concerns regarding the scope of claim 1, *i.e.*, "any mutant

recombinant microorganisms of the genus *Sinorhizobium* capable of producing vitamin B<sub>6</sub> having *any* recombinant plasmid with *any* pdxJ gene of *any* nucleotide sequence and structure from *any* biological source," is rendered moot. (Paper No. 20061205 at 4) (emphasis added).

Moreover, as is well accepted, even a "considerable amount" of experimentation is permissible if it is merely routine or if the specification provides a reasonable amount of guidance. MPEP § 2164.05 and *In re Wands*, 8 USPQ at 1404. In addition, "a patent need not teach, and preferably omits, what is well known in the art." MPEP § 2164.01 (8<sup>th</sup> ed. Rev. 5, August 2006, p. 2100-187) *citing In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

In this regard, we note that the specification provides ample disclosure sufficient to inform a skilled artisan that the Applicants enabled the currently claimed mutant recombinant microorganisms. For example, the specification discloses 5 examples and a detailed Figure 1 that provide sufficient instruction to one skilled in the art on how to make and use the currently claimed **specific** mutant recombinant microorganisms.

The specification also discloses how to obtain and use the **specific recombinant microorganisms**, *Sinorhizobium meliloti* IFO 14782/pVK601, *Sinorhizobium meliloti* PY-C341-K1, and *Sinorhizobium meliloti* PY-EGC1, recited in claim 1. The specification also discloses how to obtain and use the **specific plasmids**,

pVK100, pRK290, pLAFRI, and RSF1010, recited in claim 1. (See, e.g., Specification page 2, lines 1-5; page 3, lines 1-6; page 3, line 23 to page 4, line 18; page 5, lines 9-16; Examples 1-5, and Figure 1). Thus, identifying the mutant recombinant microorganisms capable of producing vitamin B<sub>6</sub> according to amended claim 1 is a matter of applying the disclosure in the specification of how to make such mutants and testing the pyridoxol productions of the mutants compared to *Sinorhizobium meliloti* 14782. (See Table 1). It is respectfully submitted that such activity is not undue experimentation.

For the reasons set forth above, it is respectfully submitted that the rejection has been rendered moot and should be withdrawn.

Regarding claims 3, 5, and 7, the Examiner asserted “[i]t is not apparent if the source materials to make the plasmid and microorganism recited in claims 3, 5, and 7 are both known and readily available to the public,” and “[a]n enabling deposit of the plasmid pVK100 and the microorganism *Sinorhizobium meliloti* PY-EGC1 may overcome the rejection.” (Paper No. 20061205 at 5).

Initially, we note that plasmid pVK100 is well known in the art. The designation pVK100 stands for a cosmid cloning vector having a broad host range, and it can be purchased from Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) in Gottingen, Germany. pVK100 has also been described in several articles. Attached as Exhibit 1 for the Examiner’s convenience is a printout from the Internet demonstrating that plasmid pVK100 is readily available.

As disclosed in the specification at page 5, lines 12-16, the *Sinorhizobium meliloti* PY-EGC1 strain was deposited under the terms of the Budapest Treaty at

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Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ) in Gottingen, Germany under the Deposit No.: DSM 15209, on September 17, 2002.<sup>1</sup>

For the *Sinorhizobium meliloti* PY-EGC1 deposit, the following statements are provided upon information and belief:

During the pendency of this application, access to the deposit will be afforded to the Commissioner upon request.

All restrictions imposed by the depositor on the availability to the public of the above-referenced deposited material will be irrevocably removed upon the granting of a patent.

The deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer.

The deposit will be replaced if it should ever become inviable.

Although not necessary to comply with §112, first paragraph, it is respectfully submitted that the application fully complies with the deposit requirements as set forth in 37 CFR § 1.808. Accordingly, the rejection has been rendered moot and should be withdrawn.

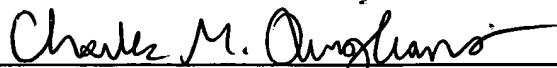
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<sup>1</sup> Attached as Exhibit 2 is a certificate from the DSMZ confirming that strain *Sinorhizobium meliloti* PY-EGC1 has been deposited under the terms of the Budapest Treaty.

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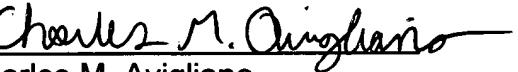
Accordingly, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on March 15, 2007.



Charles M. Avigliano, Reg. No. 52,578

Respectfully submitted,

By:   
Charles M. Avigliano  
Registration No. 52,578  
BRYAN CAVE LLP  
1290 Avenue of the Americas  
33<sup>rd</sup> Floor  
New York, NY 10104-3300  
Phone: (212) 541-2000  
Fax: (212) 541-4630